K032455

NOV - 7 2003



# 510(k) SUMMARY

1. Submitter

| | |
|---|---|
| 1) Name | KURARAY MEDICAL INC. |
| 2) Address | 1621 Sakazu, Kurashiki, Okayama 710-8622, Japan |
| 3) Contact person | Masaya Sasaki<br>Dental Material Division |
| 4) Date | August 8, 2003 |
| 5) Contact person in U.S.A. | Satoshi Yamaguchi<br>Kuraray America, Inc.<br>101 East 52nd Street, 26th Floor, New York, NY 10022<br>Telephone : (212)-986-2230 (Ext.115)<br>Facsimile : (212)-867-3543 |

2. Name of Device

| | |
|---|---|
| 1) Proprietary Name | PANAVIA F 2.0 |
| 2) Classification Name | Dental Cement (21CFR 872.3200) |
| 3) Common/Usual Name | Dental Adhesive |

3. Predicate device:

The predicate devices are as follows.

| | | | |
|---|---|---|---|
| 1. | PANAVIA F | by Kuraray Medical Inc. | (K012432) |
| 2. | CLEARFIL SE BOND | by Kuraray Medical Inc. | (K012442) |

4. Description for the premarket notification

PANAVIA F 2.0 is classified into dental cement, CFR 21 Section 872.3275, because it is a device composed of materials such as dimethacrylate monomers and inorganic fillers intended to be used for cementation of dental devices such as crown and bridges.

5. Statement of the intended use

The intended uses of this device are as follows. They are completely the same as PANAVIA F manufactured by Kuraray Medical Inc. (K012441).

1) Cementation of metal crowns and bridges, inlays and onlays
2) Cementation of porcelain crowns, inlays, onlays and veneers
3) Cementation of composite resin crowns, inlays and onlays
4) Cementation of adhesion bridges
5) Cementation of endodontic cores and prefabricated posts
6) Amalgam bonding

6. Statement of the technological characteristics and safety

6-1. Technological characteristics

This device is improved from PANAVIA F and complies with the requirement of ISO 4049:2000. The light-curing times of this device was assigned according to the type of dental curing lights. Depth of cure, thickness of surface unpolymerized layer, and sensitivity to ambient light were measured and form the result of these tests, light curing properties of this

device are superior to PANAVIA F.

6-2. Safety

All the ingredients of this device have been used the predicate devices, PANAVIA F and CLEARFIL SE BOND. Therefore the safety of this device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Kuraray Medical, Incorporated
C/O Mr. Satoshi Yamaguchi
Marketing Manager
Kuraray America, Incorporated
101 East 52nd Street, 26th Floor
New York, New York 10022

Re: K032455
Trade/Device Name: Panavia™ F 2.0
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: October 31, 2003
Received: October 31, 2003

Dear Mr. Yamaguchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

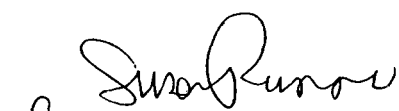
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(Premarket Notification [510(k)] Number)
510(k) Number (if known): K032455

Device Name: PANAVIA F 2.0

## Indications for Use

PANAVIA F 2.0 is indicated for the following applications:

1) Cementation of metal crowns and bridges, inlays and onlays.
2) Cementation of porcelain crowns, inlays, onlays and veneers.
3) Cementation of composite resin crowns, inlays and onlays
4) Cementation of adhesion bridges
5) Cementation of endodontic cores and prefabricated posts
6) Amalgam bonding

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Part 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032455